UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/420,092	10/18/1999	YING LUO	A-68287/DJB/	2328

20350 7590 12/18/2002

TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
FLOOD, MICHELE C	
ART UNIT	PAPER NUMBER
1654	23

DATE MAILED: 12/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/420,092	Applicant(s) Luo et al.
	Examiner Michele Flood	Art Unit 1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Oct 17, 2002*.

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *10-17, 20, and 21* is/are pending in the application.

4a) Of the above, claim(s) *10-14, 17, 20, and 21* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *15 and 16* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on October 17, 2002. Acknowledgment is made of Applicant's cancellation of Claims 18 and 19, and newly submitted Claim 21.

Claims 10-17 and 20-21 are pending in the present application.

Election/Restriction

Claims 15 and 16 reasonably read on the originally elected invention. However, Claims 10-14, 17, 20 and 21 are outside the scope of the limitations of the originally elected invention for the following reasons. As presented in the previous Office action of Paper No. 13 (dated June 6, 2001), Claims 10-14 remain withdrawn for the reasons of record. Specifically, Claims 10-14 are drawn to an non-elected invention. See previous Office action. Claims 17-20 are outside the limitations of Claims 15 and 16 because the invention of Claims 15 and 16 are drawn to a screening assay, whereas the inventions of Claims 17-20 are drawn to separate and distinct inventions. For instance, the invention of Claim 17 is drawn to a method comprising process steps and ingredients not required for the screening of a bioactive agent capable of binding to the cell cycle protein R0101; the invention of Claim 20 is drawn to a method for determining the activity of R0101 in the presence of a candidate bioactive agent; and the invention of Claim 21 is drawn a method comprising combining PCNA with cell cycle protein R0101 and the candidate bioactive agent R0101, which reads basically on a method of making a composition per se.

The newly submitted claims are directed to inventions that are independent or distinct from the invention originally claimed for the reasons set forth immediately above.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 10-14, 17, 20 and 21 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

In response to the present Office action, it is suggested that Applicant cancel Claims 10-14, 17, 20 and 21 to expedite prosecution of the instant application.

Claims 15 and 16 are under examination on the merits.

Information Disclosure Statement

The information disclosure statement filed June 2, 2002 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 101

Claims 15 and 16 are rejected under 35 U.S.C. § 101 because the claim is drawn to an invention with no apparent or disclosed specific and substantial credible utility. The instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose the biological role of this protein or its significance.

It is clear from the instant specification that the protein described therein is what is termed an "orphan protein" in the art. This is a protein whose cDNA has been isolated because of its similarity to known proteins. There is little doubt that, after complete characterization, this protein may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it has been undertaken Applicant's claimed invention is incomplete. The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The court held that:

"The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", " [u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", " [i]t is not a reward for the search, but compensation for its successful conclusion."

The instant claims are drawn to a protein of as yet undetermined function or biological significance. The claims are drawn to an isolated cell cycle protein R0101 encoding Seq. ID No.: 2. The instant specification discloses that the claimed amino acid sequence can be employed to screen bioactive agents, when the cell cycle protein R0101 is combined with a bioactive agent by determining the binding capacity of the bioactive agent to the said cell cycle protein R0101 (Seq. ID No.: 2). The specification discloses that such a screening assay can be employed to identify compounds, which act as modulators of cell cycle activity. The instant application discloses that there are a plurality of different modulators that promote, enhance or deter inhibitors of cell proliferation and that the identification of such cell cycle components and modulators is highly desirable for the therapeutic use thereof. The instant specification further discloses that there are a plurality of different mammalian proteins which are known to function as cell cycle proteins. However, neither the instant specification nor the art of record identifies even a single disease or disorder that has been shown to be associated with cell cycle protein R0101, the claimed amino acid and the protein encoded thereby can not be employed in either a screening or diagnostic capacity. For example, the instant specification incorporates by reference the teachings of

Nagase et al. (DNA Research, 1995, 2: 37-43) on page 2, lines 5-6, of the instant specification. However, there is absolutely no evidence of record or any line of reasoning that would support a conclusion that the protein of the instant invention is associated in any way with the plurality of causally unrelated cDNA sequences cited in the reference of Nagase et al. in Table 3. For instance, Applicant asserts that the instant R0101 (Seq. ID No.: 2) as a cell cycle protein without providing any evidence or examples to support such a conclusion. Thus, Applicant's assertion appears to be purely speculative and wholly unsupported by any evidence of record. Since the prior art indicates a mere 14% amino acid sequence identity to a protein without an established function of the instantly claimed cell cycle protein R0101 encoding Seq. ID No.: 2, one of ordinary skill in the art would not reasonably extrapolate or conclude a common function between structurally dissimilar proteins, much less one having 95% amino acid sequence identity to the amino acid sequence set forth in Seq. ID No.: 2 as instantly claimed by Applicant. Neither the instant specification or the art of record identifies even a single disease or disorder that has been shown to be associated with cell cycle protein R0101 of the instant invention. Since the cell cycle protein R0101 of the instant invention has not been shown to be associated with a particular physiological process that an artisan would wish to manipulate for assaying bioactive agents for the identification of compounds which bind thereto, the claimed cell cycle protein R0101 can not be used to identify compounds which would have the clinical effect of modulating processes of the cell cycle or which would be ultimately employed in a diagnostic capacity and therapeutic use thereof. Until some actual and specific significance can be attributed to the

protein identified in the specification as cell cycle protein R0101 (Seq. ID No.: 2), or the gene encoding it, the instant invention is incomplete. The protein encoded by a DNA of the instant invention is a compound known to be structurally analogous to proteins which are known in the art as cell cycle proteins. In the absence of a knowledge of the natural ligands or biological significance of this protein, there is no immediately obvious patentable use for it. To employ a protein of the instant invention in the identification of bioactive agents capable of binding to the said cell cycle protein R0101 is clearly to use it as the object of further research which has been determined by the courts to be a utility which, alone, does not support patentability. Since the instant specification does not disclose a credible "real world" use for cell cycle protein R0101 then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

Claims 15 and 16 are rejected under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to use the instant invention for those reasons given above with regard to the rejection of these claims under 35 U.S.C. § 101.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15 and 16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant speculates a method for screening for a bioactive agent capable of binding to the cell cycle protein R0101, said method comprising: (a) combining a cell cycle protein R0101 (Seq. ID No.: 2) and a candidate bioactive agent; and (b) determining the binding of said candidate bioactive agent to said cell cycle protein R0101; wherein said cell cycle protein R0101 comprises an amino acid sequence having at least about 95% identity to the amino acid sequence set forth in SEQ ID NO:2 and wherein said cell cycle protein R0101 binds to proliferating cell nuclear antigent (PCNA). The claim is further directed to a method wherein said cell cycle protein R0101 comprises the amino acid sequence set forth in SEQ ID NO:2. However, Applicant's assertion is not enabled because there is no way of determining whether the protein corresponding to (Seq. ID No.: 2) corresponds to any known protein with known activity, but for which the sequence is unknown. Therefore, the broad concept of using a cell cycle protein with (Seq. ID No.: 2) in a screening assay for determining the binding of candidate bioactive agents to the cell cycle protein R0101 is clearly beyond the skill of one of ordinary skill in the art, requiring enormous burden and experimentation without a reasonable expectation of success. Speculation does not constitute enablement.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is (703) 308-9432. The examiner can normally be reached on Monday through Friday from 7:15 am to 3:45 pm. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Brenda Brumback whose telephone number is (703) 306-3220.

MCF

December 13, 2002

CHRISTOPHER R. TATE
PRIMARY EXAMINER